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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/574,461	05/18/2000	Roger J. Talish	601-61	6818

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EXAMINER

QADERI, RUNA S

ART UNIT	PAPER NUMBER
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3737

DATE MAILED: 08/23/2004

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/574,461

Applicant(s)

TALISH ET AL.

Examiner

Runa S. Qaderi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 2/6/04.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>13</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: New claims 30-32 introduce the limitation to "wherein either said at least one ultrasound transducer or said at least one electromagnetic coil can be selectively biased relative to the other to modulate the energy" or "selectively biasing either said at least one ultrasound transducer or said at least one electromagnetic coil relative to the other to modulate said ultrasound waves." Although in light of applicant's specification Examiner interprets "selectively biasing" as placement of the two (transducer and coil(s)) or method of application of the two waves (ultrasound and electromagnetic) such that modulation is achieved, there is no antecedent basis for the limitation term in the specification.

Claim Objections

Claims 24-29 are objected to because of the following informalities: The preamble of the base claim 24 pertains to the application of ultrasonic waves whereas the body of the claim pertains to "pressure waves". The two recitations are inconsistent. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1,2,6, 8, 9,10-13,18,19, 20, 23, and 30-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Edrich et al. (US 5,476,438).

Edrich et al. teaches a method and apparatus of neuromagnetic simulation. The patent simultaneously directs focused beam of ultrasonic waves with an applied magnetic field to simulate a region of interest. Fig 3 of Edrich et al. depict a schematic of the system including ultrasound transducer source (1) which focuses the ultrasound waves into a region, coils (7) that produce magnetic fields, drivers 16 and 17 for providing a driving signal to the transducer and coil, respectively. A synchronizer (18) and delay circuit (19) perform the function of frequency and phase control of the magnetic and ultrasound signals. The synchronizer (18) and delay circuit (19), and drivers (16 and 17) function as the main operating unit for driving the ultrasound transducer and magnetic coils. The patent teaches that the system can enclose the head in a helmet-like fashion thereby satisfying the applicant's limitation to a placement module configured to be worn by the patient, column 5 lines 1-5. The coupling of driver 16 and 17 to ultrasound source and magnetic coils, respectively, as shown in figure 3

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teaches the limitation to a first and second cable. The teachings to frequency and phase control of the ultrasound and magnetic waveforms encompasses the step of varying the magnitude of the waveform as taught by applicant, column 3 line 51 through column 4 line 6. Furthermore the patent teaches that the relationship of the applied ultrasound and magnetic waves is adjusted to achieve optimum stimulation performance. To reiterate Edrich et al. teaches the direction of the acoustic waves with respect to the magnetic wave enhanced the therapeutic procedure, in that a magnetic field with a magnetic induction (flux) B orthogonal to the focused ultrasound wave will result in enhanced or improved therapy to the region of interest, column 2. The magnetic field and the ultrasound wave are applied simultaneously, furthermore a superimposition of the two waves occurs. More specifically column 2 lines 25-31 recites "the method of the invention achieves the unexpected advantage that by the superimposition of the focused ultrasound, the relatively large magnetic fields required to be effective can be directed onto a single nerve bundle..." Superimposition is defined as to lay on top. With respect to applicant's limitation of modulating the acoustic wave, the superimposition by the ultrasound of the reference means the same thing. The electromagnetic wave is laid onto to of the ultrasound wave to focus the therapy of the reference is the same thing as the ultrasound wave modulated by the electromagnetic wave. With respect to the additional limitation of "wherein either said at least one ultrasound transducer or said at least one electromagnetic coil can be selectively biased relative to the other to modulate the energy" or "selectively biasing either said at least one ultrasound transducer or said at least one electromagnetic coil relative to the other

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to modulate said ultrasound waves” of claims 30-31 Examiner directs attention to figure 3 and column 4 lines 7-10 which diagram the placement of the two and disclose that the relationship of the waves should be properly adjusted for optimum stimulation performance. In light of applicant's specification Examiner interprets “selectively biasing” as placement of the two (transducer and coil(s)) or method of application of the two waves (ultrasound and electromagnetic) such that modulation is achieved; the Edrich reference clearly satisfies the applicant's limitation. Finally the limitations to a conductive material that couples main operating unit to the at least one ultrasound transducer and at least one coil and the non-uniform magnetic field are inherent to the functionality of the invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3-5, 14,15, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Edrich et al. (US 5,476,438).

Edrich et al. teaches simultaneous application of ultrasound and magnetic waveforms to stimulate a region of interest. The patent teaches that the relationship of

the two waveforms affects the extent of therapy that is received by the tissue. Furthermore it is taught that applying the magnetic flux orthogonal to the ultrasound waveform optimizes the therapeutic procedure. Figure 3 of Edrich et al. patent is a schematic of the system, the coils 7 appear to be orthogonal to the ultrasound transducer.

The patent does not describe in angular positioning of transducer and coil with respect to each other. It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide angular descriptions because figure 3 satisfies a angle θ greater than or equal to zero and less than or equal to 90 degrees.

The patent does not explicitly recite the coil wrapped around the placement module or the transducer placed closer to treatment area than coil. It would have been obvious to a person of ordinary skill in the art to have alternatively provided these configurations so as long as the magnetic flux is orthogonal to ultrasound wave thereby enhancing or optimizing therapy as taught by Edrich et al.

Claims 7,16, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Edrich et al. (US 5,476,438) in view of Slayton et al. (6,050,943).

The system and method of Edrich et al. teaches simultaneous magnetic and ultrasound application for region stimulation. In addition Edrich column 5 lines 5-7

disclose providing feedback via CAT, MRI, or diagnostic ultrasound scanning to monitor the therapy. Edrich et al. does not teach wherein said at least one ultrasound transducer includes means for receiving reflected diagnostic data. Slayton et al. teaches a single ultrasound transducer that can both image and treat tissue. It would have been obvious to a person of ordinary skill in the art to have further to combine the teachings of Edrich and Slayton, thereby further receiving diagnostic ultrasound signals by said at least one ultrasound transducer because Edrich already discloses the advantage of providing diagnostic ultrasound to control the therapy and Slayton introduces providing the two (imaging and therapy) utilizing a single transducer which a well-known expedient in the art. The single transducer for both functions precludes from additional components within the apparatus and enables a more efficient therapeutic procedure as taught by Slayton et al.

Claims 17 and 24-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Edrich et al. (US 5,476,438) in view of Talish et al. (5,556,372).

Edrich et al. teaches a method and apparatus of neuromagnetic simulation. The patent simultaneously directs focused beam of ultrasonic waves with an applied magnetic field to simulate a region of interest. Fig 3 of Edrich et al. depict a schematic of the system including ultrasound transducer source (1) which focuses the ultrasound waves into a region, coils (7) that produce magnetic fields, drivers 16 and 17 for

providing a driving signal to the transducer and coil, respectively. A synchronizer (18) and delay circuit (19) perform the function of control means to vary the applied ultrasound and magnetic waves, column 3-4. The patent teaches that the system can enclose the head in a helmet-like fashion, column 5 lines 1-5. The teachings to adjusting the two waveforms encompass variation of the spatial distribution of the waves. Furthermore the patent teaches that the relationship of the applied ultrasound and magnetic waves is adjusted to achieve optimum stimulation performance. To reiterate Edrich et al. teaches the direction of the acoustic waves with respect to the magnetic wave enhanced the therapeutic procedure, in that a magnetic field with a magnetic induction (flux) B orthogonal to the focused ultrasound wave will result in enhanced or improved therapy to the region of interest, column 2. More specifically column 2 lines 25-31 recites "the method of the invention achieves the unexpected advantage that by the superimposition of the focused ultrasound, the relatively large magnetic fields required to be effective can be directed onto a single nerve bundle..." Superimposition is defined as to lay on top. With respect to applicant's limitation of modulating the acoustic wave, the superimposition by the ultrasound of the reference means the same thing. The electromagnetic wave is laid onto to of the ultrasound wave to focus the therapy of the reference is the same thing as the ultrasound wave modulated by the electromagnetic wave.

The patent does not teach the specific structural components of the therapeutic apparatus. Talish et al. teaches an ultrasound therapeutic apparatus, figures 1 and 3. It

would have been obvious to a person of ordinary skill in the art at the time the invention was made to have alternatively provided the coil and transducer means as the portable configuration of Talish et al. figure 3 because it allows for patient mobility while optimizing therapy. Further it can be positioned to administer therapy to any desired region rather than the helmet like structure of Edrich et al.

Response to Arguments

Applicant's arguments filed 2/6/04 have been fully considered but they are not persuasive.

CLAIM OBJECTION

Applicant's arguments do not overcome the objection. Applicant argues that the pressure wave as claimed in the body of the claim is different from the ultrasound wave claimed in the preamble. More specifically Remark page 2 recites "since both ultrasonic and electromagnetic energy are used to generate and propagate a pressure wave, then the preamble and the body of the base claim 24 are not inconsistent..." Examiner respectfully disagrees because the limitation to a pressure wave and ultrasound wave are in fact the same wave according to specification pages 12-13. Lines 10-15 of page 12 in specification is recited by applicant to give support of his argument, these lines teach the combination of the two waves. Furthermore the specification continues to describe the combination of the two waves to provide the therapy. Acoustic pressure waves, pressure wave, sound wave, ultrasound wave, and acoustic waves are used

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synonymously through the specification referring to the wave produced by the ultrasound transducer. With reference to the base claim 24, although applicant refers to a pressure wave and an ultrasound wave synonymously throughout the specification, the preamble and the body of the claims remains to be inconsistent and therefore is confusing.

102 REJECTION

Applicant argues that the Edrich et al. reference fails to anticipate the claims because it does not teach the modulated ultrasound energy. Examiner respectfully disagrees because column 2 lines 25-31 of the reference recites "the method of the invention achieves the unexpected advantage that by the superimposition of the focused ultrasound, the relatively large magnetic fields required to be effective can be directed onto a single nerve bundle..." Superimposition is defined as to lay on top. With respect to applicant's limitation of modulating the acoustic wave, the superimposition by the ultrasound of the reference means the same thing. The electromagnetic wave is laid onto to of the ultrasound wave to focus the therapy of the reference is the same thing as the ultrasound wave modulated by the electromagnetic wave.

103 REJECTION

Applicant argues that the 103 obviousness rejections in view of the respective references fails to satisfy the applicant's claims for the same reason as the anticipatory

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rejections since all the claims ultimately dependent from the anticipatory rejection.

Examiner respectfully disagrees as noted above.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Runa S. Qaderi whose telephone number is (703) 605-4285. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela D. Sykes can be reached on (703) 308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RSQ

RSQ

Angela D. Sykes

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